JAN - 8 2001

K003334

F. 510(k) Summary

Applicant:	Stick Tech Ltd, PO Box 114, 20521 Turku, Finland Tel: +358-2-2787 558 Fax: +358-2-241 0032
Contact Person:	Ilkka Kangasniemi, Ph.D.
U.S. Agent to respond to FDA requests:	William M. Troetel, Ph.D. 80 Parkway West Mount Vernon, NY 10552 Tel: (914) 664-1640 Fax: (914) 667-3993 wtroetel@westnet.com

Date Prepared:	October 19th, 2000
Device Trade Name:	Stick™ Net
Device Common Name :	Glass fiber reinforcement material
Device Classificaton Name:	Denture relining, repairing, or rebasing resin (21 CFR §872.3760)

Description of Device:

Stick™ Net is a pre-manufactured product made of glass fibers and highly porous polymer matrix for reinforcing dental acrylic polymers. **Stick™Net** is made of a thin fiberglass fabric, which increase the strength and stiffness of the final product in all directions.

Intended Use:

As reinforcement in manufacturing and/or repairing full or partial dentures as well as overdentures and orthodontic appliances.

As reinforcement for temporary and/or permanent plastic/composite partial and full crowns and bridges.

As reinforcement for customized splints used to immobilize teeth which may be required post-trauma, post-operative, or for orthodontic therapy.

Stick™ Net is substantially equivalent to Ribbond, cleared under K913040 dated October 7, 1991

Testing which has been performed on **Stick™Net** indicates that the devices have the same intended use but somewhat different technological characteristics.

Stick™Net is a polymer pre-impregnated bi-directionally continuously woven glass fiber whereas Ribbond is an ultra high modulus polyethylene fiber ribbon with no pre-impregnation. The different technological characteristics of **Stick™Net** does not raise new questions of safety and effectiveness and demonstrates that the device is as safe and effective as the predicate device.

Test results indicates that there are no hazard presented with the use of **Stick™Net** as compared with the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 8 2001

Stick Tech Limited
C/O Mr. Troetel
William M. Troetel, LLC
80 Parkway West
Mount Vernon, New York 10552

Re: K003334
Trade Name: Stick Net
Regulatory Class: II
Product Code: EBI
Dated: October 19, 2000
Received: October 25, 2000

Dear Mr. Troetel:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

B. Indications for Use

510(k) Number (if known): K003334

Device Name: Stick™Net

Indications For Use:

- As reinforcement in manufacturing and/or repairing full or partial dentures as well as overdentures and orthodontic appliances.

- As reinforcement for temporary and/or permanent plastic/composite partial and full crowns and bridges.

- As reinforcement for customized splints used to immobilize teeth which may be required for post-trauma, post-operative, or orthodontic therapy.

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003334

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use __
(Per 21 CFR 801.109)

(Optional Format 1-2-96)